K110761

MAR - 9 2012

510(k) Summary

MICT® TSH Using the MICT® Instrument

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1.	**Submitter name, address, contact**	MagnaBioSciences LLC 6325 Lusk Blvd. San Diego, CA 92121	
		Telephone: Fax:	(858)481-4400 (858-481-7410
		Contact Person:	James L. Wyatt
		Date Prepared:	February 2012
2.	**Device name**	Proprietary name:	MICT® TSH Using the MICT® Instrument
		Common name:	Magnetic ImmunoChomatographyic Test for the determination of TSH
		Classification Name:	Quantitative Determination of TSH in Human Serum
3.	**Predicate device**	Qualigen FastPack® TSH (K052301)	
4.	**Device description**	The MICT® TSH Immunoassay for the quantitative determination of TSH in human serum is designed for use on MICT® Instrument.	

MICT® TSH Device Reagents

1. Solid phase nitrocellulose membrane device with two detection zones:
    a. Control line region containing a polyclonal goat anti-rabbit IgG antibody, and
    b. Test line region containing a monoclonal anti-TSH antibody

2. Lyophilized conjugate tube containing the monoclonal anti-TSH antibody covalently coupled to 300 nm super paramagnetic particles.

The MICT® Immunoassay is a "sandwich" magnetic chromatographic assay:

- Step 1: Sample or control (100 µL) is added to the lyophilized conjugate tube and mixed using an up and down motion in the pipet.
- Set 2: Transfer the entire contents of the sample/conjugate to the sample port on the nitrocellulose test cassette.
- Step 3: The sample/conjugate will chromatograph along the nitrocellulose membrane for 30 minutes, but not longer than 45 minutes after starting the test..
- Step 4: Insert the test cassette into the MICT magnetic Instrument and press start after barcode is read.
- Results will automatically print.

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5. Intended use

The MICT® TSH is a magnetic lateral flow immunoassay for the in-vitro quantitative determination of TSH in human serum. The measurements of thyroid stimulating hormone (TSH) produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. The MICT TSH immunoassay is designed for use with the MCIT instrument. The MICT System is intended for use in clinical laboratories.

6. Comparison to Predicate Device

The following tables compare the MICT® TSH with the Qualigen FastPack® TSH.

Feature	MICT® TSH	FastPack® TSH
Intended Use.	The MICT® TSH is a magnetic lateral flow immunoassay for the in-vitro quantitative determination of TSH in human serum. The measurements of thyroid stimulating hormone (TSH) produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. The MICT System is intended for use in clinical laboratories.	FastPack® TSH Immunoassay is a paramagnetic particle immunoassay for the in-vitro quantitative determination of TSH in human plasma. The measurements of thyroid stimulating hormone (TSH) produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. The FastPack TSH Immunoassay is designed for use with the FastPack System
Assay Methodology:	Sandwich immunoassay	Sandwich immunoassay
Storage Condition:	1 – 30°C	2-8 °C
Data Analysis	Internal data reduction via microcomputer	Internal data reduction via microcomputer
Test Processing	Semi-Automated	Semi-Automated
Sample Type:	Serum	Plasma
Detector:	Magnetic Instrument	Photomultiplier Tube (PMT)
Label	Super Magnetic Particles	Alkaline Phosphatase - Lucegine
Sample Volume	100 µL	100 µL
Assay Range	0.13 to 100 µIU/mL	0.13 to 100 µIU/mL
Instrument Required	MICT® Instrument	Qualigen FastPack® System
Antibody	Monoclonal/Monoclonal	Monoclonal/Monoclonal
Solid Phase	Nitrocellulose Membrane	Magnetic Particles
Detection	Magnetic Moment	Chemiluminescence
Calibration	Factory generated master curve with single calibration per lot, calibration is stable until expiration of the assay lot.	Factory generated calibration curve using 6 standards. Recalibration required 14 day at the customer site.
Throughput	Single Sample	Single Sample
Time to Result	30 minutes	15 minutes
Reagents Supplied as	Box of 20 reagent cassettes with lyophilized conjugate tubes.	Box of 50 individual Tests

Performance Characteristics:

Feature	MICT® TSH	FastPack® TSH
Precision	Mean µIU/mL / %CV *Within Lab* Site 1 1 0.191 14.1 2 0.29 9.4 3 0.83 9.4 4 3.7 7.8 5 46.7 8.8 Site 2 1 0.191 13.3 2 0.29 10.1 3 0.87 7.8 4 4.1 9.1 5 46.6 9.5 Site 3 1 0.187 14.4 2 0.29 9.5 3 0.87 7.6 4 3.95 9.1 5 48.4 7.5	Mean µIU/mL / %CV *Total Within Lab* 1 0.54 20.0 2 1.54 9.7 3 4.69 7.0 4 46.30 9.5
Sensitivity	LOB = 0.04 µIU/mL LOD = 0.077 µIU/mL LOQ = 0.077 µIU/mL	Analytical = 0.043 µIU/mL Functional = 0.13 µIU/mL
Method Comparison	Three site performance evaluation of MICT vs. Qualigen FastPack TSH Method. Site 1: MICT = 0.97 FastPack -0.27 (n=66, r = 0.99) Site 2: MICT = 0.93 FastPack -0.07 (n=74, r = 0.99) Site 3: MICT = 0.98 FastPack 0.00 (n=64, r = 0.99) Pooled: MICT = 0.96 FastPack -0.12 (n=204, r = 0.99)	
Interfering Substances	No interference up to:	No interference up to:
Bilirubin	40 mg/dL	40 mg/dL
Hemoglobin	1000 mg/dL	1000 mg/dL
Triglycerides	3200 mg/dL	1000 mg/dL
Phospholipid	800 mg/dL	--
Specificity	500 mIU/mL LH n.d 500 mIU/mL FSH n.d. 200,000 mIU/mL hCG n.d.	500 mIU/mL LH n.d 500 mIU/mL FSH n.d. 200,000 mIU/mL hCG n.d.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

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MagnaBioSciences, LLC.
c/o James Wyatt, PhD
Chief Technical Officer
6325 Lusk Blvd.
San Diego, CA 92121

Re: k110761
Trade Name: MICT® TSH and MICT® Instrument
Regulation Number: 21 CFR §862.1690
Regulation Name: Thyroid Stimulating Hormone Test System
Regulatory Class: II
Product Codes: JLW, JJQ
Dated: February 28, 2012
Received: March 6, 2012

Dear Dr. Wyatt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K110761

Device Name: MICT® TSH

Indications for Use:

The MICT® TSH is a magnetic lateral flow immunoassay for the in-vitro quantitative determination of TSH in human serum. The measurements of thyroid stimulating hormone (TSH) produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. The MICT System is intended for use in clinical laboratories.

Prescription Use) ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K110761

Indications for Use Form

510(k) Number (if known): k110761

Device Name: MICT® Instrument

Indications for Use:

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